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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,044	08/01/2005	Giorgio Mari	7B901-002US1	5665

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EXAMINER	
BASS, DIRK R	

ART UNIT	PAPER NUMBER
1777	

NOTIFICATION DATE	DELIVERY MODE
01/05/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/525,044	MARI ET AL.	
	Examiner	Art Unit	
	DIRK BASS	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10,12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-10, 12, 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for continued examination filed December 6, 2010 is acknowledged. Claims 1, 5, 9, and 20 are amended and claims 2-4, 11, and 13 are cancelled. Claims 1, 5-10, 12, and 14-21 are pending and further considered on the merits.

Response to Amendment

In light of applicant's amendments, the examiner modifies the grounds of rejection set forth in the office action dated July 6, 2010.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 20-21** are rejected under 35 U.S.C. 102(b) as being anticipated by Ohmura et al., US 6139757 (Ohmura).

3. Regarding claim 20, Ohmura discloses a filter device for separating blood components (abstract, Example 9, fig. 1) comprising:

a. A housing (REF 3) having an inlet (REF 31) and an outlet (REF 41), more than two porous elements each comprising a set of layers of filtering material having the same filtering and hydrophilicity properties (REF 51), and each of said porous elements having a different hydrophilicity (C9/L45-55, Example 9);

b. Wherein said more than two porous elements are arranged such that a previous porous element has a higher hydrophilicity than a successive porous element in a direction of flow (C9/L63-67); and

c. The inlet porous element has a hydrophilicity value of 60 dyn/cm, the difference between the hydrophilicity of adjacent sets of two successive porous elements in a range from 2 dyn/cm to 50 dyn/cm, and the difference in

hydrophilicity between the inlet porous element and the outlet porous element being at least 20 dyn/cm (Example 9).

4. Regarding claim 21, Ohmura discloses a filter device that has a decreasing hydrophilicity profile from the inlet porous element to the final outlet porous element (Example 34).

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 1, 5-8, 10, 12, 14-15, and 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohmura et al., US 6139757 (Ohmura)..

3. Regarding claims 1 and 12, Ohmura discloses a filter device for separating blood components (abstract, Example 9, fig. 1) comprising:

a. A housing (REF 3) having an inlet (REF 31) and an outlet (REF 41), more than two porous elements each comprising a set of layers of filtering material having the same filtering and hydrophilicity properties (REF 51), and each of said porous elements having a different hydrophilicity (C9/L45-55, Example 9);

b. Wherein said more than two porous elements are arranged such that a previous porous element has a higher hydrophilicity than a successive porous element in a direction of flow (C9/L63-67); and

c. The inlet porous element has a hydrophilicity value of 60 dyn/cm, the difference between the hydrophilicity of adjacent sets of two successive porous elements in a range from 2 dyn/cm to 50 dyn/cm, and the difference in hydrophilicity between the inlet porous element and the outlet porous element being at least 10 dyn/cm (Example 9).

4. Ohmura does not disclose that the inlet porous element has a hydrophilicity rating higher than 63 dyn/cm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the porous element hydrophilicity value higher than 63 dyn/cm, since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

5. Regarding claims 5-6, Ohmura discloses that the adjacent sets of layers have a decreasing pore size from said inlet to said outlet (C9/L45-56).

6. Regarding claims 7-8, Ohmura discloses that the porous elements are constructed from hydrophilic polyurethane (Example 9).

7. Regarding claim 10, Ohmura discloses that the porous elements are arranged in the filter device according to a decreasing hydrophilicity value from said inlet to said outlet (Example 34).

8. Regarding claims 14-15 and 19, Ohmura discloses a filter device further comprising filter elements of any hydrophilicity, wherein said filter elements are microaggregate filtration elements (REF 6a-b, fig. 1).

9. Regarding claims 17-18, Ohmura discloses a method comprising feeding blood through a filter device described above (abstract).

10. **Claims 9 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohmura in view of Bormann et al., WO 00/548743 (Bormann). For purposes of clarity, the examiner is relying on the US publication of Bormann (US 6945411) for the remainder of this office action.

11. Regarding claim 9, Ohmura is relied upon in the rejection of claim 1 set forth above. Ohmura does not explicitly disclose a porous element constructed of polybutyleneterephthalate coated with a hydrophilic polymer and a second porous element constructed of polybutyleneterephthalate or polypropylene. However, Bormann discloses a filter device for the depletion of leukocytes (abstract) comprising: a housing having an inlet and an outlet (fig. 2-3), within said housing, two porous elements (REF 1, 2), each porous element comprising multiple layers of filtering material (col. 7, l. 42-50) and having different hydrophilicity (col. 8, l. 8-27), said more than two porous elements having a hydrophilicity higher than 63 dyn/cm, and a difference between the inlet porous element and the outlet porous element is at least 20 dyn/cm (col. 8, l. 8-27). Bormann further discloses the porous elements are made of polybutylene terephthalate (col. 7, l. 32-37), where first porous element can be coated with a hydrophilic polymer and the second element can be uncoated (col. 7, l. 51 – col. 8, l. 3).

12. Therefore, at the time of invention, it would have been obvious to one having ordinary skill in the art to modify the filter device of Ohmura to include the fiber materials of Bormann since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

13. Regarding claim 16, Bormann further discloses a blood bag device for the separation of blood into leukocyte depleted blood components (fig. 4), comprising a first bag (REF 51) in fluid communication with a second bag (REF 50) through a leukocyte filter device (REF 100) according to claim 1.

Response to Arguments

14. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1777

/DRB/
Dirk R. Bass